UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO:

State of Nevada v. American Home Products Corp., et al.,

D. Nev. Cause No. CV-N-02-0202-ECR

ANSWER OF NOVARTIS PHARMACEUTICALS CORPORATION TO THE STATE OF NEVADA'S AMENDED COMPLAINT

Defendant Novartis Pharmaceuticals Corporation ("Novartis"), for its Answer to the State of Nevada's Amended Complaint ("Complaint") in the captioned action, by its undersigned counsel, alleges upon knowledge as to itself, and upon information and belief as to all other matters, as follows:

T. INTRODUCTION

- 1. Admits as to the allegations set forth in numbered paragraph 1 of the Complaint that the State of Nevada purports to bring this case on behalf of the State of Nevada and persons residing in Nevada but denies that there is any basis on which to permit it to do so.
- 2. Denies the allegations set forth in numbered paragraph 2 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth, except admits that Novartis is or has been engaged in the business of manufacturing, marketing and selling prescription pharmaceuticals throughout the United States, including Nevada.
- 3. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 3 of the Complaint, except admits that the

development of new drugs can benefit Patients through better overall health, avoidance of more expensive surgical procedures, and, in some cases, longer life.

- 4. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 4 of the Complaint, except denies as to Novartis the allegations of abuses and injury to Patients, the State and its Medicaid program.
- 5. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 5 of the Complaint, except admits that certain drug reimbursement systems reimburse physicians and pharmacies for prescription drugs based upon AWPs as published and reported by third party publications.
- 6. Denies the allegations set forth in numbered paragraph 6 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 7. Denies the allegations set forth in numbered paragraph 7 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 8. Denies the allegations set forth in numbered paragraph 8 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 9. Denies the allegations set forth in numbered paragraph 9 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
 - 10. Denies the allegations set forth in numbered paragraph 10 of the Complaint.

- 11. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 11 of the Complaint.
- 12. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies the allegations set forth in numbered paragraph 12 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
 - 13. Denies the allegations set forth in numbered paragraph 13 of the Complaint.
 - 14. Denies the allegations set forth in numbered paragraph 14 of the Complaint.
 - 15. Denies the allegations set forth in numbered paragraph 15 of the Complaint.
 - 16. Denies the allegations set forth in numbered paragraph 16 of the Complaint.
 - 17. Denies the allegations set forth in numbered paragraph 17 of the Complaint
- 18. Admits as to the allegations set forth in numbered paragraph 18 of the Complaint that the State of Nevada purports to seek damages and/or restitution but denies that there is any basis on which to permit it to do so.
 - 19. Denies the allegations set forth in numbered paragraph 19 of the Complaint.
 - 20. Denies the allegations set forth in numbered paragraph 20 of the Complaint.
- 21. Admits as to the allegations set forth in numbered paragraph 21 of the Complaint that the State of Nevada purports to seek restitution through its *parens patriae* and statutory powers but denies that there is any basis on which to permit it to do so.

- 22. Admits as to the allegations set forth in numbered paragraph 22 of the Complaint that the State of Nevada purports to bring this action but denies that there is any basis on which to permit it to do so.
- 23. Admits as to the allegations set forth in numbered paragraph 23 of the Complaint that the Attorney General purports to bring this action but denies that there is any basis on which to permit him to do so.

II. PARTIES

- 24. Admits as to the allegations set forth in numbered paragraph 24 of the Complaint that the State of Nevada purports to bring this action on behalf of the State of Nevada and its residents but denies that there is any basis on which to permit it to do so.
- 25. Denies the allegations set forth in numbered paragraph 25 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 26. Admits the allegations set forth in numbered paragraph 26 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 27. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 27 of the Complaint.
- 28. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 28 of the Complaint.
- 29. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 29 of the Complaint.
- 30. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 30 of the Complaint.

- 31. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 31 of the Complaint.
- 32. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 32 of the Complaint.
- 33. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 33 of the Complaint.
- 34. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 34 of the Complaint.
- 35. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 35 of the Complaint.
- 36. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 36 of the Complaint.
- 37. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 37 of the Complaint.
- 38. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 38 of the Complaint.
- 39. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 39 of the Complaint.
- 40. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 40 of the Complaint.
- 41. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 41 of the Complaint.

- 42. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 42 of the Complaint.
- 43. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 43 of the Complaint.
- 44. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 44 of the Complaint.
- 45. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 45 of the Complaint.
- 46. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 46 of the Complaint.
- 47. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 47 of the Complaint.
- 48. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 48 of the Complaint.
- 49. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 49 of the Complaint.
- 50. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 50 of the Complaint.
- 51. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 51 of the Complaint.
- 52. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 52 of the Complaint.

- 53. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 53 of the Complaint.
- 54. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 54 of the Complaint.
- 55. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 55 of the Complaint.
- 56. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 56 of the Complaint.
- 57. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 57 of the Complaint.
- 58. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 58 of the Complaint.
- 59. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 59 of the Complaint.
- 60. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 60 of the Complaint.
- 61. Denies the allegations set forth in numbered paragraph 61 of the Complaint, except admits that Novartis has its principal place of business at One Health Plaza, East Hanover, New Jersey and that it is a U.S. affiliate of Novartis AG, which is incorporated in Switzerland and which reported a net income of \$4.2 billion on sales of \$19.1 billion in 2001.
- 62. Denies the allegations set forth in numbered paragraph 62 of the Complaint, except admits that Novartis manufactures or distributes drugs reimbursed by the Nevada Medicaid Program.

- 63. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 63 of the Complaint.
- 64. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 64 of the Complaint.
- 65. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 65 of the Complaint.
- 66. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 66 of the Complaint.
- 67. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 67 of the Complaint.
- 68. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 68 of the Complaint.
- 69. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 69 of the Complaint.
- 70. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 70 of the Complaint.
- 71. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 71 of the Complaint.
- 72. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 72 of the Complaint.
- 73. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 73 of the Complaint.

- 74. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 74 of the Complaint.
- 75. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 75 of the Complaint.
- 76. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 76 of the Complaint.

III. PRESCRIPTION DRUG SPENDING IN THE UNITED STATES HAS INCREASED DRAMATICALLY, DISPROPORTIONATELY IMPACTING THE POOR AND ELDERLY

- 77. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 77 of the Complaint.
- 78. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 78 of the Complaint.
- 79. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 79 of the Complaint.
- 80. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 80 of the Complaint.
- 81. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 81 of the Complaint.
- 82. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 82 of the Complaint.
- 83. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 83 of the Complaint.
- 84. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 84 of the Complaint.

- 85. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 85 of the Complaint.
- 86. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 86 of the Complaint.
- 87. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 87 of the Complaint.
 - 88. Denies the allegations set forth in numbered paragraph 88 of the Complaint.

IV. THE PRESCRIPTION DRUG MARKET

- 89. States that the first sentence of numbered paragraph 89 of the Complaint contains no allegations which require a response and admits the allegations set forth in the second sentence of numbered paragraph 89 of the Complaint.
- 90. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 90 of the Complaint.
- 91. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 91 of the Complaint.
- 92. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 92 of the Complaint.
- 93. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 93 of the Complaint.
- 94. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 94 of the Complaint.
- 95. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 95 of the Complaint.

- 96. Denies the allegations set forth in numbered paragraph 96 of the Complaint, except admits that WAC is the price Novartis charges to a wholesaler, before discounts.
- 97. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 97 of the Complaint, except admits that certain drug reimbursement systems reimburse physicians and pharmacies for prescription drugs based upon AWPs as published and reported by third party publications.
- 98. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 98 of the Complaint.
- 99. Denies the allegations set forth in numbered paragraph 99 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 100. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 100 of the Complaint.
- 101. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 101 of the Complaint.
- 102. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 102 of the Complaint.
- 103. Denies the allegations set forth in numbered paragraph 103 of the Complaint, except admits that certain health plans, HMOs and employers contract with Pharmacy Benefit Managers ("PBMs") to process pharmaceutical claims and manage drug utilization and "formularies."
- 104. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 104 of the Complaint.

- 105. Denies the allegations set forth in numbered paragraph 105 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 106. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 106 of the Complaint.

V. GOVERNMENT REIMBURSEMENT SYSTEMS FOR PRESCRIPTION DRUGS

- 107. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 107 of the Complaint.
 - 108. Admits the allegations set forth in numbered paragraph 108 of the Complaint.
- 109. Admits the allegations set forth in numbered paragraph 109 of the Complaint and states that none of the Novartis products named in the Complaint is a Medicare Part B covered drug.
- 110. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 110 of the Complaint and states that none of the Novartis products named in the Complaint is a Medicare Part B covered drug.
- 111. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 111 of the Complaint and further respectfully refers the Court to 42 C.F.R. § 405.517 for a full and complete reading of its provisions.
- 112. Admits that the quoted language set forth in numbered paragraph 112 of the Complaint appeared in a prior regulation and may have at some point in the past been a statement of law but is not now, and admits that the AWP published in the *Red Book* or other compendia has been used as a ceiling for Medicare reimbursement.

- 113. Admits the allegations set forth in numbered paragraph 113 of the Complaint and further respectfully refers the Court to 42 C.F.R. § 405.517 for a full and complete reading of its provisions.
- 114. As to the allegations set forth in numbered paragraph 114 of the Complaint admits that the Medicare Program has publicly announced that it would use the AWP published in third party pricing compendia as the basis for reimbursement and further respectfully refers the Court to Program Memorandum AB-99-63 for a full and complete reading of its contents.
- 115. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 115 of the Complaint and further respectfully refers the Court to Program Memorandum AB-99-63 for a full and complete reading of its contents.
- 116. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 116 of the Complaint, except admits that there are no regulations describing how AWPs are to be calculated, nor any regulatory process for approving them, and that it reports certain pricing information to independent publishing companies.
- 117. Admits the allegations set forth in numbered paragraph 117 of the Complaint and states that none of the Novartis products named in the Complaint is a Medicare Part B covered drug.
- 118. Admits the allegations set forth in numbered paragraph 118 of the Complaint and states that none of the Novartis products named in the Complaint is a Medicare Part B covered drug.
- 119. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 119 of the Complaint.

- 120. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 120 of the Complaint.
- 121. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 121 of the Complaint.
- 122. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 122 of the Complaint.
- 123. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 123 of the Complaint.
- 124. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 124 of the Complaint and further respectfully refers the Court to 42 C.F.R. § 440.120 for a full and complete reading of its provisions.
- 125. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 125 of the Complaint.
- 126. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 126 of the Complaint.

VI. AWP PLAYS A CENTRAL ROLE IN ALL PRESCRIPTION DRUG REIMBURSEMENT SYSTEMS, AND THE TRUTHFUL REPORTING OF AWPS IS ESSENTIAL TO THE INTEGRITY OF THE MARKETPLACE

- 127. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 127 of the Complaint.
- 128. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 128 of the Complaint.
- 129. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 129 of the Complaint.

- 130. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 130 of the Complaint, except admits that there are several pharmaceutical industry compendia that purport to publish AWPs.
- Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and further respectfully refers the Court to the forward to the 1999 edition of the *Red Book*, the referenced June 1996 Dow Jones news article and the Dey Complaint for a full and complete reading of their contents.
 - 132. Denies the allegations set forth in numbered paragraph 132 of the Complaint.
- 133. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 133 of the Complaint and further respectfully refers the Court to the Office of the Inspector General's April 2003 report "Compliance Program Guidance for Pharmaceutical Manufacturers" for a full and complete reading of its contents.
- 134. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 134 of the Complaint and further respectfully refers the Court to the Office of the Inspector General's April 2003 report "Compliance Program Guidance for Pharmaceutical Manufacturers" for a full and complete reading of its contents.
 - 135. Denies the allegations set forth in numbered paragraph 135 of the Complaint.

VII. THE AWP INFLATION SCHEME

- 136. Denies the allegations set forth in numbered paragraph 136 of the Complaint.
- 137. Denies the allegations set forth in numbered paragraph 137 of the Complaint.
- 138. Denies the allegations set forth in numbered paragraph 138 of the Complaint.
- 139. Denies the allegations set forth in numbered paragraph 139 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth

of the allegations set forth therein, except admits that, from time to time during the relevant period, Novartis provided price lists to third party publications which contained, *inter alia*, "AWPs" for certain of its drugs and, from at least 1997 to the present, stated that AWP is not intended to be a price charged by Novartis for any product to any customer.

- 140. Denies the allegations set forth in numbered paragraph 140 of the Complaint.
- 141. Denies the allegations set forth in numbered paragraph 141 of the Complaint.
- 142. Denies the allegations set forth in numbered paragraph 142 of the Complaint.
- 143. Denies the allegations set forth in numbered paragraph 143 of the Complaint.
- 144. Denies the allegations set forth in numbered paragraph 144 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 145. Denies the allegations set forth in numbered paragraph 145 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 146. Denies the allegations set forth in numbered paragraph 146 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 147. Denies the allegations set forth in numbered paragraph 147 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 148. Denies the allegations set forth in numbered paragraph 148 of the Complaint and states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint.

- 149. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 149 of the Complaint and states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint.
- 150. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 150 of the Complaint, states that none of the Novartis products named in the Complaint is a Medicare Part B covered drug, states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint, and further respectfully refers the Court to 42 C.F.R. § 405.517 for a full and complete reading of its provisions.
- 151. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 151 of the Complaint, states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint, and further respectfully refers the Court to 42 C.F.R. § 447.332(b) for a full and complete reading of its provisions.
- 152. Denies the allegations set forth in numbered paragraph 152 of the Complaint and states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint.
- 153. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 153 of the Complaint and states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint.

- 154. Denies the allegations set forth in numbered paragraph 154 of the Complaint and states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint.
- 155. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 155 of the Complaint and states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint.
- 156. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 156 of the Complaint and states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint.
- 157. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 157 of the Complaint and states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint.
- 158. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 158 of the Complaint and states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint.
- 159. Denies the allegations set forth in numbered paragraph 159 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and states that none of the Novartis products named in the

Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint.

- Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint, and further respectfully refers the Court to the Dey Complaint for a full and complete reading of its contents.
- 161. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 161 of the Complaint and further respectfully refers the Court to the Dey Complaint for a full and complete reading of its contents.
- 162. Denies the allegations set forth in numbered paragraph 162 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and further respectfully refers the Court to the Dey Complaint for a full and complete reading of its contents.
- 163. Denies the allegations set forth in numbered paragraph 163 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and further respectfully refers the Court to the Dey Complaint for a full and complete reading of its contents.
- 164. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 164 of the Complaint.
- 165. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 165 of the Complaint.

- 166. Denies the allegations set forth in numbered paragraph 166 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 167. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 167 of the Complaint.
- 168. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 168 of the Complaint.
- 169. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 169 of the Complaint and states that none of the Novartis products named in the Complaint is a generic drug as defined in the first sentence of numbered paragraph 92 of the Complaint.
- 170. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 170 of the Complaint.
- 171. Denies the allegations set forth in numbered paragraph 171 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 172. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 172 of the Complaint and further respectfully refers the Court to the referenced 2003 Wall Street Journal article for a full and complete reading of its contents.
- 173. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 173 of the Complaint, except admits that it is aware

of published reports of investigations by various government entities relating to pharmaceutical pricing.

- 174. As to the truth of the allegations set forth in numbered paragraph 174 of the Complaint denies the existence of, and its participation in, any "scheme" and further respectfully refers the Court to the September 28, 2000 letter from the House of Representatives Committee on Ways and Means, Subcommittee on Health to the President of the Pharmaceutical Research and Manufacturers of America for a full and complete reading of its contents.
- 175. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 175 of the Complaint and further respectfully refers the Court to the September 28, 2000 letter from the House of Representatives Committee on Ways and Means, Subcommittee on Health to the President of the Pharmaceutical Research and Manufacturers of America for a full and complete reading of its contents.
- 176. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 176 of the Complaint.
 - 177. Denies the allegations set forth in numbered paragraph 177 of the Complaint.
- 178. Denies the allegations set forth in numbered paragraph 178 of the Complaint, except admits that the State of Nevada purports to bring its action for the identified drugs and further states that, pursuant to the Court's June 10, 2004 Memorandum and Order and Fed. R. Civ. P. 9(b), the State may not maintain claims as to any drug for which it has not stated an alleged fraudulent AWP.
- 179. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 179 of the Complaint.

- 180. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 180 of the Complaint.
- 181. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 181 of the Complaint.
- 182. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 182 of the Complaint.
- 183. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 183 of the Complaint.
- 184. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 184 of the Complaint.
- 185. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 185 of the Complaint.
- 186. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 186 of the Complaint.
- 187. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 187 of the Complaint.
- 188. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 188 of the Complaint.
- 189. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 189 of the Complaint.
- 190. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 190 of the Complaint.

- 191. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 191 of the Complaint.
- 192. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 192 of the Complaint.
- 193. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 193 of the Complaint.
- 194. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 194 of the Complaint.
- 195. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 195 of the Complaint.
- 196. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 196 of the Complaint.
- 197. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 197 of the Complaint.
- 198. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 198 of the Complaint.
- 199. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 199 of the Complaint.
- 200. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 200 of the Complaint.
- 201. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 201 of the Complaint.

- 202. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 202 of the Complaint.
- 203. Denies the allegations set forth in numbered paragraph 203 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 204. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 204 of the Complaint.
- 205. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 205 of the Complaint.
- 206. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 206 of the Complaint.
- 207. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 207 of the Complaint.
- 208. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 208 of the Complaint.
- 209. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 209 of the Complaint.
- 210. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 210 of the Complaint.
- 211. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 211 of the Complaint.
- 212. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 212 of the Complaint.

- 213. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 213 of the Complaint.
- 214. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 214 of the Complaint.
- 215. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 215 of the Complaint.
- 216. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 216 of the Complaint.
- 217. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 217 of the Complaint.
- 218. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 218 of the Complaint.
- 219. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 219 of the Complaint.
- 220. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 220 of the Complaint.
- 221. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 221 of the Complaint.
- 222. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 222 of the Complaint.
- 223. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 223 of the Complaint.

- 224. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 224 of the Complaint.
- 225. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 225 of the Complaint.
- 226. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 226 of the Complaint.
- 227. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 227 of the Complaint.
- 228. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 228 of the Complaint.
- 229. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 229 of the Complaint.
- 230. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 230 of the Complaint.
- 231. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 231 of the Complaint.
- 232. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 232 of the Complaint.
- 233. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 233 of the Complaint.
- 234. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 234 of the Complaint.

- 235. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 235 of the Complaint.
- 236. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 236 of the Complaint.
- 237. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 237 of the Complaint.
- 238. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 238 of the Complaint.
- 239. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 239 of the Complaint.
- 240. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 240 of the Complaint.
- 241. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 241 of the Complaint.
- 242. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 242 of the Complaint.
- 243. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 243 of the Complaint.
- 244. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 244 of the Complaint.
- 245. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 245 of the Complaint.

- 246. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 246 of the Complaint.
- 247. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 247 of the Complaint.
- 248. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 248 of the Complaint.
- 249. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 249 of the Complaint.
- 250. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 250 of the Complaint.
- 251. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 251 of the Complaint.
- 252. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 252 of the Complaint.
- 253. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 253 of the Complaint.
- 254. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 254 of the Complaint.
- 255. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 255 of the Complaint.
- 256. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 256 of the Complaint.

- 257. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 257 of the Complaint.
- 258. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 258 of the Complaint.
- 259. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 259 of the Complaint.
- 260. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 260 of the Complaint.
- 261. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 261 of the Complaint.
- 262. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 262 of the Complaint.
- 263. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 263 of the Complaint.
- 264. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 264 of the Complaint.
- 265. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 265 of the Complaint.
- 266. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 266 of the Complaint.
- 267. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 267 of the Complaint.

- 268. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 268 of the Complaint.
- 269. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 269 of the Complaint.
- 270. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 270 of the Complaint.
- 271. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 271 of the Complaint.
- 272. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 272 of the Complaint.
- 273. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 273 of the Complaint.
- 274. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 274 of the Complaint.
- 275. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 275 of the Complaint.
- 276. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 276 of the Complaint.
- 277. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 277 of the Complaint.
- 278. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 278 of the Complaint.

- 279. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 279 of the Complaint.
- 280. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 280 of the Complaint.
- 281. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 281 of the Complaint.
- 282. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 282 of the Complaint.
- 283. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 283 of the Complaint.
- 284. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 284 of the Complaint.
- 285. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 285 of the Complaint.
- 286. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 286 of the Complaint.
- 287. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 287 of the Complaint.
- 288. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 288 of the Complaint.
- 289. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 289 of the Complaint.

- 290. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 290 of the Complaint.
- 291. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 291 of the Complaint.
- 292. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 292 of the Complaint.
- 293. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 293 of the Complaint.
- 294. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 294 of the Complaint.
- 295. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 295 of the Complaint.
- 296. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 296 of the Complaint.
- 297. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 297 of the Complaint.
- 298. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 298 of the Complaint.
- 299. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 299 of the Complaint.
- 300. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 300 of the Complaint.

- 301. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 301 of the Complaint.
- 302. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 302 of the Complaint.
- 303. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 303 of the Complaint.
- 304. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 304 of the Complaint.
- 305. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 305 of the Complaint.
- 306. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 306 of the Complaint.
- 307. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 307 of the Complaint.
- 308. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 308 of the Complaint.
- 309. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 309 of the Complaint.
- 310. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 310 of the Complaint.
- 311. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 311 of the Complaint.

- 312. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 312 of the Complaint.
- 313. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 313 of the Complaint.
- 314. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 314 of the Complaint.
- 315. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 315 of the Complaint.
- 316. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 316 of the Complaint.
 - 317. Denies the allegations set forth in numbered paragraph 317 of the Complaint.
- 318. Denies the allegations set forth in numbered paragraph 318 of the Complaint, except admits that the State purports to seek relief for the identified drugs, but denies that there is any basis upon which to permit it to do so and further states that, pursuant to the Court's June 10, 2004 Memorandum and Order and Fed. R. Civ. P. 9(b), the State may not maintain claims as to any drug for which it has not stated an alleged fraudulent AWP.
 - 319. Denies the allegations set forth in numbered paragraph 319 of the Complaint.
 - 320. Denies the allegations set forth in numbered paragraph 320 of the Complaint.
 - 321. Denies the allegations set forth in numbered paragraph 321 of the Complaint.
 - 322. Denies the allegations set forth in numbered paragraph 322 of the Complaint.
 - 323. Denies the allegations set forth in numbered paragraph 323 of the Complaint.
 - 324. Denies the allegations set forth in numbered paragraph 324 of the Complaint.

- 325. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 325 of the Complaint.
- 326. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 326 of the Complaint.
- 327. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 327 of the Complaint.
- 328. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 328 of the Complaint.
- 329. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 329 of the Complaint.
- 330. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 330 of the Complaint.
- 331. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 331 of the Complaint.
- 332. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 332 of the Complaint.
- 333. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 333 of the Complaint.
- 334. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 334 of the Complaint.
- 335. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 335 of the Complaint.

- 336. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 336 of the Complaint.
- 337. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 337 of the Complaint.
- 338. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 338 of the Complaint.
- 339. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 339 of the Complaint.
- 340. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 340 of the Complaint.
- 341. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 341 of the Complaint.
- 342. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 342 of the Complaint.
- 343. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 343 of the Complaint.
- 344. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 344 of the Complaint.
- 345. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 345 of the Complaint.
- 346. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 346 of the Complaint.

- 347. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 347 of the Complaint.
- 348. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 348 of the Complaint.
- 349. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 349 of the Complaint.
- 350. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 350 of the Complaint.
- 351. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 351 of the Complaint.
- 352. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 352 of the Complaint.
- 353. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 353 of the Complaint.
- 354. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 354 of the Complaint.
- 355. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 355 of the Complaint.
- 356. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 356 of the Complaint.
- 357. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 357 of the Complaint.

- 358. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 358 of the Complaint.
- 359. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 359 of the Complaint.
- 360. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 360 of the Complaint.
- 361. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 361 of the Complaint.
- 362. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 362 of the Complaint.
- 363. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 363 of the Complaint.
- 364. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 364 of the Complaint.
- 365. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 365 of the Complaint.
- 366. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 366 of the Complaint.
- 367. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 367 of the Complaint.
- 368. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 368 of the Complaint.

- 369. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 369 of the Complaint.
- 370. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 370 of the Complaint.
- 371. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 371 of the Complaint.
- 372. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 372 of the Complaint.
- 373. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 373 of the Complaint.
- 374. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 374 of the Complaint.
- 375. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 375 of the Complaint.
- 376. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 376 of the Complaint.
- 377. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 377 of the Complaint.
- 378. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 378 of the Complaint.
- 379. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 379 of the Complaint.

- 380. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 380 of the Complaint.
- 381. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 381 of the Complaint.
- 382. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 382 of the Complaint.

VIII. DEFENDANTS' "BEST PRICE" FRAUDS

- 383. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis admits the allegations set forth in numbered paragraph 383 of the Complaint and further respectfully refers the Court to 42 U.S.C. § 1396r-8 for a full and complete reading of its provisions.
- 384. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 384 of the Complaint.
- 385. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis states that numbered paragraph 385 of the Complaint contains no allegations which require a response.
- 386. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 386 of the Complaint and

further respectfully refers the Court to 42 U.S.C. § 1396r-8(c)(3) for a full and complete reading of its provisions.

- 387. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 387 of the Complaint and further respectfully refers the Court to 42 U.S.C. § 1396r-8(k) and to the model Rebate Agreement for a full and complete reading of their provisions.
- 388. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 388 of the Complaint and further respectfully refers the Court to 42 U.S.C. § 1396r-8(c) for a full and complete reading of its provisions.
- 389. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 389 of the Complaint and further respectfully refers the Court to 42 U.S.C. § 1396r-8(c) and to the model Rebate Agreement for a full and complete reading of their provisions.
- 390. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies knowledge or information sufficient to form a

belief as to the truth of the allegations set forth in numbered paragraph 390 of the Complaint and further respectfully refers the Court to the Office of the Inspector General's April 2003 report "Compliance Program Guidance for Pharmaceutical Manufacturers" for a full and complete reading of its contents.

- 391. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 391 of the Complaint and further respectfully refers the Court to the Office of the Inspector General's April 2003 report "Compliance Program Guidance for Pharmaceutical Manufacturers" for a full and complete reading of its contents.
- 392. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies the allegations set forth in numbered paragraph 392 of the Complaint.
- 393. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies the allegations set forth in numbered paragraph 393 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 394. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies knowledge or information sufficient to form a

belief as to the truth of the allegations set forth in numbered paragraph 394 of the Complaint and further respectfully refers the Court to the Office of the Inspector General's March 2001 report "Medicaid Drug Rebates - Sales to Repackagers Excluded from Best Price Determinations" for a full and complete reading of its contents.

- 395. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies the allegations set forth in numbered paragraph 395 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 396. Denies the allegations set forth in numbered paragraph 396 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 397. States that numbered paragraph 397 of the Complaint contains no allegations which require a response.
- 398. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 398 of the Complaint.
- 399. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 399 of the Complaint.
- 400. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 400 of the Complaint.
- 401. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 401 of the Complaint.

- 402. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 402 of the Complaint.
- 403. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 403 of the Complaint.

IX. DEFENDANTS' CONCEALMENT OF THE TRUTH AND TOLLING OF STATUTES OF LIMITATION

- 404. Denies the allegations set forth in numbered paragraph 404 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- Admits the allegations set forth in numbered paragraph 405 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and further respectfully refers the Court to the CMS Health Care Industry Market Update (dated January 10, 2003) for a full and complete reading of its contents.
- A06. Denies the allegations set forth in numbered paragraph 406 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, except admits that Novartis has confidentiality agreements with its customers to protect its proprietary information.
- 407. Denies the allegations set forth in numbered paragraph 407 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
 - 408. Denies the allegations set forth in numbered paragraph 408 of the Complaint.

- 409. Denies the allegations set forth in numbered paragraph 409 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 410. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 410 of the Complaint.
 - 411. Denies the allegations set forth in numbered paragraph 411 of the Complaint.
 - 412. Denies the allegations set forth in numbered paragraph 412 of the Complaint.

X. DIRECT DAMAGE SUSTAINED BY THE STATE OF NEVADA, PATIENTS AND THIRD-PARTY PAYORS

- 413. Denies the allegations set forth in numbered paragraph 413 of the Complaint.
- 414. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 414 of the Complaint.
 - 415. Denies the allegations set forth in numbered paragraph 415 of the Complaint.
- 416. States that numbered paragraph 416 of the Complaint contains no allegations which require a response.
 - 417. Denies the allegations set forth in numbered paragraph 417 of the Complaint.
- 418. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the first sentence of numbered paragraph 418 of the Complaint and otherwise denies the allegations set forth therein.
 - 419. Denies the allegations set forth in numbered paragraph 419 of the Complaint.
- 420. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies the allegations set forth in numbered paragraph

420 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

- 421. Denies the allegations set forth in numbered paragraph 421 of the Complaint.
- 422. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the first sentence of numbered paragraph 422 of the Complaint and otherwise denies the allegations set forth therein.

XI. CLAIMS FOR RELIEF

COUNT I

DECEPTIVE TRADE PRACTICES (Violations of NRS 598.0903, et seq.)

CLAIM FOR DAMAGES CAUSED TO NEVADA RESIDENTS

- 423. Repeats and incorporates by reference its responses to numbered paragraphs one through 422 above.
- 424. Admits as to numbered paragraph 424 of the Complaint that the State of Nevada purports to assert Count I on behalf of Nevada residents but denies that there is any basis upon which to permit it to do so.
- 425. Denies the allegations set forth in numbered paragraph 425 and subparagraphs 425(a)-(d) of the Complaint.
 - 426. Denies the allegations set forth in numbered paragraph 426 of the Complaint.
 - 427. Denies the allegations set forth in numbered paragraph 427 of the Complaint.
 - 428. Denies the allegations set forth in numbered paragraph 428 of the Complaint.
 - 429. Denies the allegations set forth in numbered paragraph 429 of the Complaint.

COUNT II

DECEPTIVE TRADE PRACTICES DIRECTED AT ELDERLY NEVADA RESIDENTS (Violations of NRS 598.0973)

CLAIM FOR CIVIL PENALTIES AND INJUNCTIVE RELIEF

- 430. Repeats and incorporates by reference its responses to numbered paragraphs one through 429 above.
- 431. Admits as to numbered paragraph 431 of the Complaint that the State of Nevada purports to bring Count II but denies that there is any basis upon which to permit it to do so.
- 432. Denies the allegations set forth in numbered paragraph 432 and subparagraphs 432(a)-(d) of the Complaint.
 - 433. Denies the allegations set forth in numbered paragraph 433 of the Complaint.
 - 434. Denies the allegations set forth in numbered paragraph 434 of the Complaint.
 - 435. Denies the allegations set forth in numbered paragraph 435 of the Complaint.
 - 436. Denies the allegations set forth in numbered paragraph 436 of the Complaint.

COUNT III

DECEPTIVE TRADE PRACTICES (Violations of NRS 598.0903, et seq.)

CLAIM FOR CIVIL PENALTIES, INJUNCTIVE RELIEF, AND RESTITUTION FOR THE STATE OF NEVADA

- 437. Repeats and incorporates by reference its responses to numbered paragraphs one through 436 above.
- 438. Admits as to numbered paragraph 438 of the Complaint that the State of Nevada purports to bring Count III but denies that there is any basis upon which to permit it to do so.
- 439. Denies the allegations set forth in numbered paragraph 439 and subparagraphs 439(a)-(d) of the Complaint and further states that the allegations set forth in numbered paragraph 439 and subparagraphs 439(a)-(d) are most as to Novartis to the extent that they relate

to "Best Price" pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs related to "Best Price."

- 440. Denies the allegations set forth in numbered paragraph 440 of the Complaint and further states that the allegations set forth in numbered paragraph 440 are moot as to Novartis to the extent that they relate to "Best Price" pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs related to "Best Price."
- 441. Denies the allegations set forth in numbered paragraph 441 of the Complaint and further states that the allegations set forth in numbered paragraph 441 are moot as to Novartis to the extent that they relate to "Best Price" pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs related to "Best Price."
- 442. Denies the allegations set forth in numbered paragraph 442 of the Complaint and further states that the allegations set forth in numbered paragraph 442 are moot as to Novartis to the extent that they relate to "Best Price" pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs related to "Best Price."
- 443. Denies the allegations set forth in numbered paragraph 443 of the Complaint and further states that the allegations set forth in numbered paragraph 443 are moot as to Novartis to the extent that they relate to "Best Price" pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs related to "Best Price."

COUNT IV

RACKETEERING (Violations of NRS 207.400, et seq.)

CLAIM FOR TREBLE DAMAGES TO STATE OF NEVADA AND CIVIL FORFEITURE

- 444. States that the allegations set forth in numbered paragraph 444 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 445. States that the allegations set forth in numbered paragraph 445 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 446. States that the allegations set forth in numbered paragraph 446 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 447. States that the allegations set forth in numbered paragraph 447 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 448. States that the allegations set forth in numbered paragraph 448 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 449. States that the allegations set forth in numbered paragraph 449 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.

- 450. States that the allegations set forth in numbered paragraph 450 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 451. States that the allegations set forth in numbered paragraph 451of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 452. States that the allegations set forth in numbered paragraph 452of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 453. States that the allegations set forth in numbered paragraph 453 and subparagraphs 453(a)-(m) of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 454. States that the allegations set forth in numbered paragraph 454 and subparagraphs 454(a)-(f) of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 455. States that the allegations set forth in numbered paragraph 455 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 456. States that the allegations set forth in numbered paragraph 456 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.

- 457. States that the allegations set forth in numbered paragraph 457 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 458. States that the allegations set forth in numbered paragraph 458 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 459. States that the allegations set forth in numbered paragraph 459 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 460. States that the allegations set forth in numbered paragraph 460 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 461. States that the allegations set forth in numbered paragraph 461 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 462. States that the allegations set forth in numbered paragraph 462 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 463. States that the allegations set forth in numbered paragraph 463 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.

- 464. States that the allegations set forth in numbered paragraph 464 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 465. States that the allegations set forth in numbered paragraph 465 of the Complaint are most pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.
- 466. States that the allegations set forth in numbered paragraph 466 of the Complaint are moot pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count IV of the Complaint.

COUNT V

MEDICAID FRAUD (Violations of NRS 422.540, et seq.)

CLAIM FOR COST RECOVERY AND CIVIL PENALTIES

- 467. Repeats and incorporates by reference its responses to numbered paragraphs one through 466 above.
- 468. Admits as to numbered paragraph 468 of the Complaint that the State of Nevada purports to bring Count V but denies that there is any basis upon which to permit it to do so.
- 469. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis admits the allegations set forth in numbered paragraph 469 of the Complaint as to Novartis and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 470. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent

that any response is required, Novartis denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 470 of the Complaint.

- 471. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 471 and subparagraphs 471(a)-(c) of the Complaint.
- 472. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis admits the allegations set forth in numbered paragraph 472 of the Complaint.
- 473. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies the allegations set forth in numbered paragraph 473 of the Complaint.
- 474. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies the allegations set forth in numbered paragraph 474 of the Complaint.
- 475. Plaintiff's "Best Price" claims against Novartis have been dismissed by the Court's Order dated June 10, 2004 and, therefore, no response to this allegation is required; to the extent that any response is required, Novartis denies the allegations set forth in numbered paragraph 475 of the Complaint.

- 476. Denies the allegations set forth in numbered paragraph 476 of the Complaint and further states that the allegations set forth in numbered paragraph 476 are moot as to Novartis to the extent that they relate to "Best Price" pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count V of the Complaint related to "Best Price."
- 477. Denies the allegations set forth in numbered paragraph 477 of the Complaint and further states that the allegations set forth in numbered paragraph 477 are moot as to Novartis to the extent that they relate to "Best Price" pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims by plaintiffs in Count V of the Complaint related to "Best Price."

COUNT VI

PUNITIVE DAMAGES

CLAIM BROUGHT ON BEHALF OF THE STATE OF NEVADA

- 478. Repeats and incorporates by reference its responses to numbered paragraphs one through 477 above.
- 479. Denies the allegations set forth in numbered paragraph 479 of the Complaint, and further states that the allegations set forth in numbered paragraph 479 are most as to Novartis to the extent that they relate to "Best Price" pursuant to the Court's Memorandum and Order dated June 10, 2004 in which the Court dismissed all claims related to "Best Price."

XII. DEMAND FOR JURY TRIAL

Novartis denies plaintiff is entitled to a judgment or any other relief requested in the Prayer for Relief.

NOVARTIS PHARMACEUTICALS CORPORATION'S AFFIRMATIVE DEFENSES

The pleading of these affirmative defenses does not relieve plaintiff of its burdens to prove each and every element of its claims and the damages, if any, to which it is entitled. As and for its affirmative defenses, Novartis alleges as follows:

FIRST AFFIRMATIVE DEFENSE

480. Plaintiff fails to state a claim against Novartis upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

481. Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

THIRD AFFIRMATIVE DEFENSE

482. Plaintiff has no standing or capacity to bring some or all of the claims raised in this suit, including but not limited to, plaintiff's asserted status in *parens patriae* to recover Medicaid or Medicare expenditures or to seek injunctive relief.

FOURTH AFFIRMATIVE DEFENSE

483. Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Novartis as alleged in the Complaint.

FIFTH AFFIRMATIVE DEFENSE

484. To the extent plaintiff or any of its citizens for whom it is seeking relief obtains recovery in any other case predicated on the same factual allegations, plaintiff is barred from seeking recovery against Novartis based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

SIXTH AFFIRMATIVE DEFENSE

485. Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Nevada.

SEVENTH AFFIRMATIVE DEFENSE

486. Plaintiff fails to allege with particularity its civil conspiracy claims against Novartis as required by Fed. R. Civ. P. 9(b).

EIGHTH AFFIRMATIVE DEFENSE

487. Plaintiff's claims are barred, in whole or in part, to the extent that plaintiff or any of its citizens for whom it is seeking relief has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

NINTH AFFIRMATIVE DEFENSE

488. Any and all actions taken by Novartis with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

TENTH AFFIRMATIVE DEFENSE

489. Plaintiff's claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

ELEVENTH AFFIRMATIVE DEFENSE

490. Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

TWELFTH AFFIRMATIVE DEFENSE

491. Plaintiff's claims against Novartis are barred because Novartis has complied with all applicable regulations of the federal and state governments.

THIRTEENTH AFFIRMATIVE DEFENSE

492. Plaintiff's claims against Novartis are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

FOURTEENTH AFFIRMATIVE DEFENSE

493. Plaintiff's claims are barred, in whole or in part, because they violate Novartis' rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Constitution of the State of Nevada, insofar as plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

FIFTEENTH AFFIRMATIVE DEFENSE

494. Novartis' statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by plaintiff.

SIXTEENTH AFFIRMATIVE DEFENSE

495. Plaintiff fails to state with particularity facts to support the fraud allegations, and fails to plead with particularity the fraudulent concealment and multi-source medicine allegations against Novartis contained in the Complaint.

SEVENTEENTH AFFIRMATIVE DEFENSE

A96. Plaintiff's claims against Novartis are barred, in whole or in part, because Novartis did not make any false statements to plaintiff or any of the citizens for whom plaintiff is seeking relief. As to any statement asserted against Novartis that plaintiff alleges to be false or misleading, Novartis had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

EIGHTEENTH AFFIRMATIVE DEFENSE

497. To the extent that plaintiff attempts to seek equitable relief against Novartis, it is not entitled to such relief because it has an adequate remedy at law.

NINETEENTH AFFIRMATIVE DEFENSE

498. Plaintiff's claims against Novartis for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

TWENTIETH AFFIRMATIVE DEFENSE

499. Plaintiff's claims for injunctive relief against Novartis are barred by the doctrines of *in pari delicto* and/or unclean hands.

TWENTY-FIRST AFFIRMATIVE DEFENSE

500. The acts complained of in the Complaint are ancillary to legitimate, procompetitive activity.

TWENTY-SECOND AFFIRMATIVE DEFENSE

501. Novartis' conduct was not intended to have, did not have and was not likely to have had any adverse effects on competition in any relevant market.

TWENTY-THIRD AFFIRMATIVE DEFENSE

502. Plaintiff's claims against Novartis are barred, in whole or in part, with respect to any alleged overcharge or supra-competitive price because such supra-competitive price, if any, was absorbed, in whole or part, by a person and/or entity which purchased the medicine directly, and/or by an intermediate indirect purchaser, and was not passed through to plaintiff.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

503. Plaintiff's claims against Novartis are barred, in whole or in part, due to its failure to join indispensable parties.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

504. Plaintiff's claims against Novartis are barred, in whole or in part, because it has suffered no damages as a result of the matters alleged in the Complaint.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

505. Plaintiff's claims are barred, in whole or in part, because any injuries sustained by plaintiff were the result of its own conduct or the intervening or superceding conduct of third parties.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

because it failed to mitigate its damages, and its failure to mitigate damages should proportionately reduce the recovery of plaintiff and the allocation of any fault, if any exists, attributable to Novartis; (2) because it would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; (3) by the doctrine of consent and/or ratification to the extent that plaintiff has received and paid for products manufactured, marketed and sold by Novartis after the filing of plaintiff's original Complaint; and (4) because they are speculative and remote and because of the impossibility of ascertaining and allocating of those alleged damages.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

507. Novartis is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by plaintiff, with respect to the same alleged injuries.

TWENTY-NINTH AFFIRMATIVE DEFENSE

59

508. Any damages recovered by the plaintiff from Novartis must be limited by the applicable statutory ceilings on recoverable damages.

THIRTIETH AFFIRMATIVE DEFENSE

509. Plaintiff fails to allege facts or a cause of action against Novartis sufficient to support a claim for attorneys' fees, double damages and/or legal fees.

THIRTY-FIRST AFFIRMATIVE DEFENSE

510. To the extent punitive damages are sought, plaintiff's punitive damages claims against Novartis: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against Novartis; (3) cannot be sustained because the laws regarding the standards for determining liability for and the amount of punitive damages fail to give Novartis prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed, and are void for vagueness in violation of Novartis' Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of Nevada; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Novartis' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and laws of the State of Nevada; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Novartis for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Novartis' products would constitute impermissible multiple punishments for the same wrong, in violation of Novartis' Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law, and statutory laws of the State of Nevada; (6) cannot be sustained because any award of punitive damages

without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Novartis' Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of Nevada; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according Novartis the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Novartis' rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of Nevada.

THIRTY-SECOND AFFIRMATIVE DEFENSE

against Novartis cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Novartis; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with

sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding plaintiff's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Novartis' Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law, and public policies of the State of Nevada.

THIRTY-THIRD AFFIRMATIVE DEFENSE

512. To the extent punitive damages are sought, plaintiff's claim for punitive damages against Novartis cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Novartis' due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Novartis' right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law, and public policies of the State of Nevada.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

513. Novartis adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

514. Novartis hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

515. Plaintiff's claims against Novartis for damages with regard to multiple-source products are inconsistent with the laws of mathematics and conflict with plaintiff's liability theory.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

516. Plaintiff's claims against Novartis are barred because Novartis did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

517. Plaintiff's claims against Novartis are barred because Novartis did not directly or indirectly engage in any conduct in violation of state or federal law.

THIRTY-NINTH AFFIRMATIVE DEFENSE

518. Novartis denies that plaintiff has valid consumer protection claims against Novartis under Nevada state law. However, if such claims are found to exist, Novartis pleads all available defenses under the applicable laws.

FORTIETH AFFIRMATIVE DEFENSE

519. Any allegedly fraudulent statements or conduct of Novartis did not directly or proximately cause the alleged injuries as required under state consumer protection laws of Nevada.

FORTY-FIRST AFFIRMATIVE DEFENSE

520. Novartis' conduct was not "deceptive" as required under Nevada consumer protection laws.

FORTY-SECOND AFFIRMATIVE DEFENSE

521. Plaintiff did not rely on the allegedly fraudulent statements or conduct of Novartis as required under the Nevada consumer protection laws.

FORTY-THIRD AFFIRMATIVE DEFENSE

522. Any allegedly fraudulent statement or conduct of Novartis was not consumeroriented as required under the Nevada consumer protection laws.

FORTY-FOURTH AFFIRMATIVE DEFENSE

523. Since at least 1997 Novartis has affirmatively stated on its published price lists that the AWP reported on its lists was not intended to be a price charged by Novartis for any product to any customer. Novartis thus disclosed in its price announcements that reported AWPs for Novartis drugs did not, and were not intended to, represent the actual price paid by purchasers of such products. Accordingly, plaintiffs are estopped from claiming to have been defrauded by virtue of any action by Novartis.

FORTY-FIFTH AFFIRMATIVE DEFENSE

524. Some or all of plaintiff's claims against Novartis arise from plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

WHEREFORE, defendant Novartis Pharmaceuticals Corporation demands that: (1) the Complaint be in all respects dismissed as to it; (2) it be awarded its costs of defending this action, including its reasonable attorneys' fees; and (3) it be awarded such other and further relief as the Court may deem just and proper.

Dated: Boston, Massachusetts July 12, 2004

Respectfully submitted,

/s/ Karen F. Green Karen F. Green, BBO # 209050 WILMER CUTLER PICKERING HALE AND DORR LLP 60 State Street Boston, Massachusetts 02109 (617) 526-6000

Jane W. Parver (admitted pro hac vice)
Saul P. Morgenstern (admitted pro hac vice)
Rachel H. Yarkon (admitted pro hac vice)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
(212) 836-8000

Attorneys for Defendant Novartis Pharmaceuticals Corporation